

REMARKS/ARGUMENTS

Claims 1-18, 20, and 22-29 are currently pending in this application, claim 22 was withdrawn from consideration and claims 1-18, 20, and 23-29 were rejected. The specification has been amended on pages 16-19 merely to include the sequence ID nos. from the sequence listing for the sequence recited on those pages to comply with the requirements of 37 CFR 1.821 through 1.825. No new matter has been added by including the sequence identifiers with the sequences recited on pages 16-19 of the specification. Claim 1 has been amended to recite that the recombinant polynucleotide comprises the *kstD* promoter from *Rhodococcus* and a nucleotide sequence encoding a heterologous polypeptide that is operably linked to said promoter. Support for the amendments to claim 1 can be found in claim 7 as originally filed and in the specification on page 4, lines 10-11. Claim 7 has been canceled and claims 8-10 have been amended merely to maintain proper dependency. Claim 16 has been amended merely to correct a typographical error. Reconsideration and allowance of the claims is respectfully requested in view of the foregoing amendments and the following remarks.

1. Sequence Compliance

The Examiner asserts that the application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). According to the Examiner however the application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences are set forth in the specification that lack sequence identifiers. In response applicants have amended the specification on pages 16 to 19 to include the sequence ID nos. (SEQ ID NOs) for each of the sequences recited on those pages. The SEQ ID NOs for each of the recited sequences correspond with the sequences listed in the previously submitted Sequence Listing (in both paper and computer readable format, the sequence listing recorded on the computer readable form being identical to the paper copy of the sequence listing). No new matter has been added by including the sequence identifiers with the sequences recited on pages 16-19 of the specification. For these reasons applicants submit that the application as amended complies with the requirements of 37 CFR 1.821 through 1.825.

2. Claims 1-6 are rejected under 35 U.S.C. § 102(b), as allegedly being anticipated.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by van de Geize et al., FEMS Micorbiol. Leet. 205, 2001, 197-202 (van der Geize I hereinafter). Claims 1-6 are also rejected under 35 U.S.C. 102(b) as allegedly being anticipated by van de Geize et al., Appl. Environ. Micorbiol., 66, 2000, 2029-2036 (van der Geize II hereinafter). According to the Examiner, van der Geize I discloses a recombinant polynucleotide comprising the *kstD* promoter from *Rhodococcus*, which includes the promoter region shown in nucleotides 1-158 of SEQ ID NO:3 or a functional part thereof (see Fig. 2, plasmid pSDH200). Further, the Examiner asserts that van der Geize II discloses a recombinant polynucleotide comprising the *kstD* promoter from *R. erythropolis*, and further comprising a nucleotide sequence encoding a transcription regulator of said promoter, which is *kstR* gene, and which is controlled by steroidal compounds (see page 2031, pSDH200 for instance; see Fig. 2; see page 2035, left col., paragraph 2).

In response, applicants have amended claim 1 to recite to recite that the recombinant polynucleotide comprises the *kstD* promoter from *Rhodococcus* and a nucleotide sequence encoding a heterologous polypeptide that is operably linked to said promoter. Applicants submit that neither van der Geize I nor van der Geize II discloses a recombinant polynucleotide comprising in addition to the *kstD* promoter a nucleotide sequence encoding a heterologous polypeptide that is operably linked to said promoter. Therefore, claim 1, as amended is not anticipated by van der Geize I or van der Geize II, and neither are claims 2 to 6 by virtue of their dependency from claim 1, as the cited references do not disclose the claimed invention. Accordingly, applicants respectfully request withdrawal of the rejections under 35 U.S.C. 102(b).

3. Claims 1, 3-18, 20, and 23-29 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing comply with the written description requirement.

Claims 1, 3-18, 20, and 23-29 are rejected under 35 U.S.C. 112, first paragraph as allegedly failing to comply with the written description requirement as set forth on pages 4-6 of the Office Action. According to the Examiner, to provide evidence of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The Examiner list factors to be considered including disclosure of complete or partial structure,

physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. The Examiner asserts that the claimed invention is directed to any recombinant polynucleotide comprising a kstD promoter from any *Rhodococcus*, as well as any nucleotide sequence encoding a transcription regulator of said promoter (kstR) and any homologue or a functional part thereof. According to the Examiner, the specification has adequate written description of the promoter kstD from *R. erythropolis*, and the kstR gene of *R. erythropolis*, there is no disclosure on the structural limitations of the genus represented by the functional parts of the promoter, or homologues of the kstR gene, which identifies regions that must be maintained, or which may be varied and result in a functional molecule. Further, the Examiner also asserts that there is no disclosure on the structural limitations of the genus represented by functional parts of SEQ ID NO:6, or methods of testing the function thereof. According to the Examiner, one skilled in the art would conclude that the disclosure of *R. erythropolis* kstD promoter, and kstR gene, and SEQ ID NO:6 is not representative of the undefined genus of homologues and fragments recited in the claims. The Examiner concludes that the inventor therefore, at the time the application was filed was not in possession of the broad genus comprising kstD promoters from any *Rhodococcus*, functional parts of the *R. erythropolis* kstD promoter, and functional parts and homologues of kstR gene of *R. erythropolis*, and functional parts of SEQ ID NO:6 needed to practice the claimed invention.

In response, applicants submit that specification clearly describes the claimed invention including a genus of kstD promoters from *Rhodococcus*, functional parts thereof or describes methods to determine functional parts thereof. Also are described in reasonable detail are the kstR gene and functional parts and homologues thereof and functional parts of SEQ ID NO:6 or methods are described to determine such functional parts thereof. The kstD promoter is functionally well defined in the specification. The kstD gene is a promoter for the expression of the kstD1 gene which resides in the kstD locus. The kstD1 gene product has 3-ketosteroid Δ^1 dehydrogenase activity (KSTD activity) which is essential in steroid degradation. Accordingly, functional parts of the kstD promoter can be determined with techniques to the skilled artisan, as is also described in the examples of the specification. Preferably, the kstD promoter gene comprises the nucleotide sequence of 158 base pairs according to SEQ ID NO:3 or a shortened

version thereof (e.g. deleted at the 5' end) which will still possess the functional capacity of a promoter. The functional capacity may be determined following the experimentation in the examples of the specification as described above, also see p. 10 of the specification. Further, the *kstR* gene is described in the specification as a regulatory gene carrying the consensus sequence of repressor proteins of the TetR family, thereby providing additional structural description of the *kstR* gene and functional parts or homologues thereof. Applicants note that SEQ ID NO:6 is a polypeptide sequence of the repressor protein *kstR*. In view hereof, applicants submit that the specification conveys to the skilled artisan that the inventors were in possession of the entire genus of the claimed invention at the time the application was filed, including *kstD* promoters from any *Rhodococcus*, functional parts of the *R. erythropolis* *kstD* promoter, and functional parts and homologues of *kstR* gene of *R. erythropolis*, and functional parts of SEQ ID NO:6.

For these reasons, applicants submit that the claimed subject matter is reasonably described in the specification in such a way as to reasonably convey to the skilled artisan that the inventors had possession thereof at the time the application was filed. Accordingly, applicants respectfully request withdrawal of the rejection.

4. Claim 16 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement. According to the Examiner, it is apparent that *R. erythropolis* RG10 is required to practice the invention. The Examiner asserts that as such the cell must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. In response, applicants submit that the bacterium *Rhodococcus erythropolis* RG10 has been deposited with a recognized depository under accession number DSMZ 15231 with the DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen. The deposit of the biological material was made according to PCT Rule 13bis, the pending application being a National Stage application of International Application PCT/EP2003/050928. Accordingly, applicants submit that *R. erythropolis* RG10 will be readily available to the public

upon granting of the patent. Accordingly, applicants respectfully request withdrawal of the rejection.

It is believed that claims 1-6, 8-18, 20, and 23-29 are now in condition for allowance, early notice of which would be appreciated. If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same.

Respectfully submitted,

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